

REMARKS

Reconsideration and withdrawal of the rejections of the claimed invention is respectfully requested in view of the amendments, remarks and enclosures herewith, which place the application in condition for allowance.

I. STATUS OF CLAIMS AND FORMAL MATTERS

Claims 1-10 are now pending in this application. The elements represented by new claims 7-10 are supported in the specification, e.g., paragraph [0016] and the Examples of the U.S. publication of the application (U.S. Patent Application Publication 2007-0020323 – “the ‘323 publication”). No new matter has been added by this amendment.

It is submitted that the claims, herewith and as originally presented, are patentably distinct over the prior art cited in the Office Action, and that these claims were in full compliance with the requirements of 35 U.S.C. § 112.

II. THE 35 U.S.C. 112, 2nd PARAGRAPH REJECTION HAS BEEN OVERCOME

Claims 1 and 6 were rejected as allegedly indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regards as the invention. The applicants request reconsideration of this rejection for the following reasons.

The rejection of claim 1 has been addressed by the amendments to claim 1 made above.

The applicants presume that the reference to “shading elevations” referred to claim 6 instead of claim 1 as indicated in the Office Action. In order to expedite prosecution, the applicants have adopted the language of paragraph [0025] of the ‘323 publication.

III. THE 35 U.S.C. 103(a) REJECTION HAS BEEN OVERCOME

Claims 1-6 were rejected as allegedly being obvious over Bocchialini et al. (WO 98/58685 – “Bocchialini”) in view of Hoffman et al. (U.S. Patent 5,254,348 – “Hoffman”). The applicants request reconsideration of this rejection for the following reasons.

Preliminary notes:

- (1) No reference was made to Hoffmann in the explanation of the rejection and as such the applicants presume that the rejection was intended to be made over Bocchialini alone.
- (2) Although this application does not qualify for participation in the patent prosecution highway (PPH), Director Kappos clearly is in favor of extended use of this program.¹

¹ “[The USPTO is] also focused on global worksharing – which I believe is key to helping us meet the increasing challenge of efficiently managing the USPTO’s workload. We need to **increase participation** in worksharing projects such as the Patent Prosecution Highway **by orders of magnitude**, so we can truly see the benefits of worksharing.”

With this in mind, the applicants note that in the EPO (a PPH participant), the parallel EP application has been allowed (see EP 1648551).

A. The differences between Bocchialini and the applicants' claimed plaster have not been properly addressed when considering Bocchialini and the claimed plaster as a whole

As reiterated by the Supreme Court in *KSR International Co. v. Teleflex Inc. (KSR)*, 550 U.S. 398, 82 USPQ2d 1385 (2007), the framework for the objective analysis for determining obviousness under 35 U.S.C. 103 is stated in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966). Obviousness is a question of law based on underlying factual inquiries. The factual inquiries enunciated by the Court are as follows:

- (A) Determining the scope and contents of the prior art;
- (B) Ascertaining the differences between the prior art and the claims in issue;
- (C) Resolving the level of ordinary skill in the art; and
- (D) Evaluating evidence of secondary considerations.

When ascertaining the differences between the prior art and the claims in issue, both the claimed invention and the prior art are considered as a whole. Once the *Graham* factual inquiries are resolved, Office personnel must determine whether the claimed invention would have been obvious to one of ordinary skill in the art.

Bocchialini refers to a plaster for transdermal delivery comprising a transparent backing layer and a transparent adhesive layer that contains the active substance. This plaster is described as having the characteristics of having “mechanical strength, flexibility, transparency and electric conductivity.” The backing layer is obtained by spreading evenly a certain amount of the above mentioned composition on a thermo-resistant glass plate and drying the layer. After drying, a flexible, transparent, gas-permeable and electrically conductive backing is obtained (page 6-7, lines 32-34).

The rejection apparently gives a broad interpretation of the term “optical lens”. However, it is well known that the scope of the claimed invention must be clearly determined by giving the claims the “broadest reasonable interpretation consistent with the specification.” See *Phillips v. AWH Corp.*, 415 F.3d 1303, 1316, 75 USPQ2d 1321, 1329 (Fed. Cir. 2005). More

including time and cost savings for applicants and patent offices worldwide.”(emphasis added) excerpt from remarks to IPO Annual Conference by USPTO Director David Kappos (“The USPTO – Early Views and Initiatives of the

recently, “[t]he broadest-construction rubric coupled with the term “comprising” does not give the PTO an unfettered license to interpret claims to embrace anything remotely related to the claimed invention. Rather, claims should always be read in light of the specification and teachings in the underlying patent. *See Schreiber-Schroth Co. v. Cleveland Trust Co.*, 311 U.S. 211, 217 (1940).” *In re Suitco* (Fed. Cir. – April 14, 2010)

As applied to the applicants’ claims, one of ordinary skill in the art would reasonably interpret the applicants specific description of optical lenses in their specification as being equivalent to the transparent backing layer of Bocchialini.

Moreover, there is no indication that Bocchialini intended the transparent backing layer as a layer comprises a multiplicity of optical lenses organized in a planar arrangement. There is no teaching of suggestion that this transparent backing could be seen as “one” lens which has the property focusing light of an external light source onto the stratum corneum of the skin, in order to generate stratum corneum changes and therefore to improve the permeability of the skin. A transparent backing layer in combination of a laser beam does not lead to the applicants’ claimed plaster nor would it lead one of ordinary skill in the art to think that Bocchialini teaches the transparent backing layer containing a multiplicity of optical positive lenses organized in a planar arrangement.

B. Modification of Bocchialini’s invention in the manner described by the applicants’ plaster would change the principle of operation of Bocchialini’s invention and constitutes a teaching away from the claimed plaster

It is well known that “[i]f the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious. *In re Ratti*, 270 F.2d 810, 123 USPQ 349 (CCPA 1959).”)

As stated above, the invention of Bocchialini leads to a product which has “mechanical strength, flexibility, transparency and electric conductivity.” Substituting or adding optical lenses into the transparent backing layer at the very least would reduce the electrical conductivity required in Bocchialini’s invention and also would likely result in a reduction in mechanical strength and flexibility.

Moreover, the transparent backing layer of Bocchialini is meant to accommodate the transmission of light via a laser beam, i.e. the focusing of light upon a very specific point whereas the optical lenses of the invention can accommodate a wide variety of light sources and transmit that light to the skin over a much wider area.

For these reasons, modifying Bocchialini in the manner described in the Office Action would significantly change the operation of Bocchialini's invention and as such the applicants' claimed plaster is unobvious for this reason alone.

C. Optimization of ranges argues is inapplicable to Bocchialini

MPEP 2144.04 states that "...if the facts in a prior legal decision are sufficiently similar to those in an application under examination, the examiner may use the rationale used by the court."

While no case law citation as made, the argument with respect to "optimization of parameters" is clearly related to the guidance provided in MPEP 2144.05, section II. (Optimization of Ranges), subsection A. (Optimization within Prior Art Conditions or Through Routine Experimentation).²

However, this section relates to the optimization of *ranges not parameters*. There are no ranges disclosed within Bocchialini which can be optimized to arrive at the applicants' claimed invention.

Even if Bocchialini had disclosed a range for some variable (e.g. an amount of incident light to penetrate the skin), the very next section of MPEP 2144.05 states that only result-effective variables can be optimized, i.e. "[a] particular parameter must first be recognized as a result-effective variable, i.e., a variable which achieves a recognized result, before the determination of the optimum or workable ranges of said variable might be characterized as routine experimentation. *In re Antonie*, 559 F.2d 618, 195 USPQ 6 (CCPA 1977). See MPEP 2144.05, section II.B. There is nothing within Bocchialini which suggests that optimization of a light focal point was a result effective variable especially in light of the fact that Bocchialini is using a laser beam, a highly focused light source.

² "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955) (Claimed process which was performed at a temperature between 40°C and 80°C and an acid concentration between 25% and 70% was held to be *prima facie* obvious over a reference process which differed from the claims only in that the reference process was performed at a temperature of 100°C and an acid concentration of 10%.)

Therefore, Bocchialini does not provide a basis for establishing a *prima facie* holding of obviousness because all elements of the applicants' plaster have not been taught or suggested and modification of Bocchialini in the manner taught by the applicants' plaster would represent a teaching away from Bocchialini's invention.

CONCLUSION

In view of the above, reconsideration and withdrawal of the restriction requirement is respectfully requested. It is also believed that the application is in condition for allowance, and favorable consideration of the application and prompt issuance of a Notice of Allowance are earnestly solicited. Favorable action is earnestly solicited.

Respectfully submitted,
FROMMER LAWRENCE & HAUG LLP

By: /Howard C. Lee/
Marilyn M. Brogan Howard C. Lee
Reg. No. 31,223 Reg. No. 48,104
Telephone: (212) 588-0800
Facsimile: (212) 588-0500